Department of Vermont Health Access
Pharmacy Benefit Management Program
**DUR Board Meeting Minutes**
January 17, 2017

**Board Members:**

**Present:**

| | | |
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| Zail Berry, MD | Clayton English, PharmD | Bill Breen, RPh |
| Patricia King, MD | Meghan Groth, PharmD | Louise Rosales, NP |

**Absent:**
Alisson Richards, MD

**Staff:**

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|---|---|---|
| Michael Ouellette, RPh, Change Healthcare | MaryBeth Bizzari, RPH, DVHA | Laurie Brady, RPh, Change HealthCare |
| Jeffrey Barkin, MD, Change Healthcare | Jennifer Egelhof, DVHA | |
| | Thomas Simpatico, MD, DVHA | |

**Guests:**

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| Thomas Algozzine, Novartis | Adam Denman, GSK | John Kirby, Sanofi |
| Richard Angeli, Merck | Christine Dube, MedImmune | Margaret Glassman, Alkermes |
| Kristen Bruno-Doherty, Astrazeneca | Jai Persico, SunPharma | Lance Nicholls, Pfizer |
| | Katherine Chiari, Shire | Patrick Jones, Ipsen |
| Jeffrey Olson, Gilead | Franco Casagrande, Abbvie | Julia Shaw, Vermont Legal |
| Paul Short, Vertex | Rodney Francisco, Sunovion | Marc Vincent, Merck |
| Scott Williams, J & J | | |

**1. Executive Session:**

- An executive session was held from 6:00 p.m. until 6:25p.m.

**2. Introductions and Approval of DUR Board Minutes:**

- Welcomed new DUR board member Meghan Groth.
- Introductions were made around the table.
- The December meeting minutes were accepted as printed.

**3. DVHA Pharmacy Administration Updates: Jennifer Egelhof, DVHA and Michael Skaar, Pharmacy Intern, DVHA:**

- **Discussion of Act 172, Sec. E.306.11 – Prescribing Practices; Drug Utilization Review Board; Report**
  - "The Drug Utilization Review Board in the Department of Vermont Health Access shall analyze data from prescriptions dispensed to Medicaid beneficiaries, including prescriptions written to treat mental health conditions, to determine whether health care providers routinely follow the U.S. Food and Drug Administration's recommended dosage amounts. The Drug Utilization Review Board shall report its findings and any recommendations to the House Committees on Appropriations, on Health Care, and on Human Services and the Senate Committees on Appropriations and Health and Welfare."
  - DVHA presented the proposed analysis which will include drugs in the list of top 10 drugs by cost and volume for State Fiscal Year 2017, at least 2 of which will be mental health drugs. Members of the DUR board asked why the analysis was being limited to 10 drugs as they were unsure if this would give the true picture of prescribing habits. DVHA responded that this was done to make it a more manageable analysis. The DUR board also questioned what the concerns of the legislature are and also wanted to know what the information is going to be used for. They stated that medications are often prescribed above FDA recommended doses when there is clinical justification or literature based evidence to support such dosing. DVHA advised that they would attempt to obtain more details from the legislature. Change Healthcare will commence with the analysis, and the results will be presented at the February 21st meeting of the DUR board.

**4. Medical Director Update: Thomas Simpatico, MD, DVHA**

- Interviews are ongoing for a new medical director.
- A brief introduction and background of the new Secretary of Human Services and Commissioner of DVHA was provided.

**5. Follow-up Items from Previous Meetings:**

- None at this time.

**6. RetroDUR/DUR: Laurie Brady, RPh Change Healthcare**

- **Introduce: Long Term use of Skeletal Muscle Relaxants**
  - Skeletal muscle pain is a frequent complaint in clinical practice. Numerous treatment options exist, including topical agents, NSAIDs, antidepressants, anticonvulsants, anesthetic and steroid injections, DMARDs, and muscle relaxants. Generally, muscle relaxants should be used for 2-3 weeks to treat acute pain, per guidelines and the prescribing information provided by the drug manufacturers. They generally are not recommended for use in the elderly population, and there are many possible drug-drug interactions and side effects that make skeletal muscle relaxants potentially dangerous. We propose to examine the use of skeletal muscle relaxants among Vermont Medicaid members, specifically looking at members who have been prescribed these medications for longer than 30 consecutive days. We are also interested in identifying members who have been co-prescribed opioids and/or benzodiazepines within the same 30-day period. We will use paid, non-reversed Medicaid

pharmacy and medical claims date from calendar years 2015-2016, excluding members with Part D, VMAP, and Healthy Vermonters coverage. We will identify members using skeletal muscle relaxants (carisoprodol, chlorzoxazone, cyclobenzaprine, metaxalone, methocarbamol, and orphenadrine) for more than 30 days within a 90-day period. We will also look for users on more than 90 days cumulatively in a year. We will exclude anti-spasticity agents typically used to treat spasticity caused by neurological disorders (baclofen, tizanidine, and dantrolene). We will look at these members to see if they are co-prescribed an opioid or benzodiazepine within the same time period. We will also note the top medical diagnoses on file for these members. We will identify the prescribers for the outliers to see if this is a widespread practice requiring general education outreach or if there are a select number of prescribers who may need intervention.

**Board Decision:** The board decided to not exclude any drug. They would like to exclude patients with a neurological diagnosis instead.

- **Data presentation: Compliance with GLP-1 Agonists in Type II Diabetes**
  - GLP-1 (glucagon-like peptide 1 receptor) agonists are incretin mimetics which have several benefits for diabetes management. They suppress post-prandial glucagon release, delay stomach emptying, and increase insulin sensitivity. Significantly lower rates of hypoglycemia accompany GLP-1 therapy than many alternative hypoglycemics including insulin and sulfonylureas. This class also has the side effect of modest weight reduction and reduction of systolic blood pressure. Although they improve glycemic control, there are few long-term studies of GLP-1 agonists to assess clinically important health outcomes (cardiovascular events, mortality), durability of weight loss, or safety. Many questions remain unanswered regarding clinical use in type 2 diabetes, including long-term benefits and risks and their role in combination with other diabetes medications. Medical claims were evaluated to look for a diagnosis of type II DM. From those patients identified, pharmacy claims were then used to look for members who were prescribed a GLP-1 medication (exenatide, liraglutide, albiglutide, dulaglutide). The data was examined using a standard measure of compliance, the medication possession ratio (MPR). The type and number of additional diabetic medications used concurrently with GLP-1 therapy was also evaluated.

    Paid. Non-reversed Medicaid pharmacy and medical claims from SFY 2015 and 2016 were analyzed, and members with Part D, VMAP, and Healthy Vermonters coverage were excluded. The results showed 418 unique members identified as users of a GLP-1 agonist. Of those, 47 were tried on more than one GLP-1 agonist or different strengths of the same GLP-1 agonist, so there were a total of 465 member/medication combinations. 332 (71.4%) had an MPR > 0.8 which is considered adherent. 133 (28.6%) had an MPR < 0.8, which could indicate that approximately 30% of the time members are not adherent to their GLP-1 agonist as prescribed. The majority of patients (96%) who changed to a different strength or GLP-1 medication, had an MPR > 0.8 for at least one of the GLP-1

agonists. 307 members had at least 1 other anti-diabetic prescription filled concurrently with their GLP-1 agonist. 169 members had at least 2 other anti-diabetic medications, and 111 patients were identified as being on a GLP-1 agonist only.

Consideration for action: Further claims level analysis could be done for the 133 cases where the MPR was <0.8. The initial duration of prior authorization approval could be shortened, and claims analysis could be done with renewal requests to assess compliance. Stricter criteria for prior authorization approval could also be considered.

**Board Decision:** No action at this time.

**7. Review of Newly-Developed/Revised Clinical Coverage Criteria and/or Preferred Products**

- None at this time

**8. Clinical Update: Drug Reviews: Jeffery Barkin, MD Change Healthcare and Laurie Brady RPh, Change Healthcare**

**Abbreviated New Drug Reviews:**

- None at this time.

**Full New Drug Reviews:**

**a) Afstyla® (antihemophilic factor, recombinant)**

- Afstyla is a new longer acting factor eight product. It is a single chain molecule devised using recombinant technology. It can be used in adults and children for the treatment of bleeding. In looking at Afstyla in reference to other products, there were no head to head comparisons or superiority studies.

**Recommendation:**

- Add Afstyla to non-preferred.
- Move Koate-DVI from von Willebrand to Factor VIII sub-category. It was miss categorized before.
- Remove Vial or Kit specifications from PDL.

**Board Decision:** The Board unanimously approved the above recommendation.

**b) Bevespi® (glycopyrrolate/formoterol)**

- Bevespi® Aerosphere is a metered-dose inhaler that contains the combination of micronized glycopyrrolate (an anticholinergic) and micronized formoterol

fumarate (a long-acting beta2-adrenergic agonist or LABA). Glycopyrrolate is a long-acting antimuscarinic (often referred to as an anticholinergic) that works through inhibition of the M3 receptor at the smooth muscle, leading to bronchodilation. Formoterol is a LABA with a rapid onset of action that acts locally in the lungs as a bronchodilator. It is indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. It is not indicated for the relief of acute bronchospasm or for the treatment of asthma. The safety and efficacy of Bevespi® Aerosphere were assessed in 8 dose-ranging studies and 2 placebo-controlled lung function trials. The two confirmatory trials will be discussed here. Trial 1 and Trial 2 were both 24-week, randomized, double-blind, placebo-controlled, parallel-group trials that included subjects with moderate to very severe COPD to assess the efficacy of treatment on lung function. Results suggested that in both trials, Bevespi® Aerosphere demonstrated a larger increase in mean change from baseline of trough FEV1 as compared to placebo, glycopyrrolate, and formoterol. It is the first LAMA/LABA combination delivered in a metered-dose inhaler; however, it is not the first available LAMA/LABA combination. There is no evidence at this time to support that Bevespi® Aerosphere is safer or more effective than the currently available combination medications or a single agent LAMA and LABA taken concurrently.

**Recommendation:**

- Add Bevespi® Aerosphere to non-preferred with quantity limit of 1 inhaler/30 days.
- Move Stiolto Respimat® to preferred with quantity limit of 3 inhaler/90 days.
    - Clinical criteria
        - Add Bevespi Aerosphere to the Anoro Ellipta criteria
        - Remove Stiolto Respimat from clinical criteria.

*Public Comment:* Christine Dube, MedImmune: Highlighted attributes of Bevespi® Aerosphere.

**Board Decision:** The Board unanimously approved the above recommendation.

**c) Vonvendi® (von Willebrand factor, recombinant)**

- Vonvendi® (von Willebrand factor [Recombinant]) is indicated for on-demand treatment and control of bleeding episodes in adults diagnosed with VWD. It can

be administered with or without recombinant factor VIII. Vonvendi® is the only product that is exclusively von Willebrand factor, containing no factor VIII. It can be used alone, although it is recommended to use in combination with a factor VIII product in a bleeding patient whose baseline factor VIII levels are less than 40% or whose levels are unknown. We also looked to see if there were any head to head trials or superiority trials and were unable to find any.

**Recommendation:**

- Add Vonvendi® to non-preferred
  - Clinical criteria are consistent for all non-preferred products: The prescriber must provide a clinically compelling reason for the use of the requested medication including reasons why any of the preferred products would not be suitable alternatives.

*Public Comment:* Daniel Shaw, Shire: Highlighted the attributes of Vonvendi®.

**Board Decision:** The Board unanimously approved the above recommendation.

**d) Briviact® (brivaracetam)**

- Briviact® is indicated as adjunctive therapy in the treatment of partial-onset seizures in patients ≥16 years of age with epilepsy. Brivaracetam, the active ingredient of Briviact®, has a high and selective affinity for synaptic vesicle protein 2A (SV2A) in the brain. While the exact mechanism of action by which Briviact® exerts its anticonvulsant activity is not known, it is thought its affinity for SV2A may contribute to its anticonvulsant effect. There were 3 randomized, double-blind, placebo-controlled studies to assess the safety and efficacy of Briviact® when used as adjunctive therapy in adults with partial-onset seizures, with or without secondary generalization. Patients included were those with partial-onset seizures not adequately controlled with 1-2 concomitant antiepileptic drugs, and the median baseline seizure frequency across the 3 studies was 9 seizures per 28 days. The primary outcome in Study 1 and Study 2 was the % reduction in 7-day partial-onset seizure frequency over placebo. For Study 3, the primary outcome was the % reduction in 28-day partial-onset seizure frequency over placebo. Results suggested that statistically significant reductions were seen with Briviact® over placebo for the primary outcome in Study 2 and 3 ($p<0.05$). In Study 1 and 2, about 20% of patients were on concurrent levetiracetam. While the number of patients was limited, Briviact® did not provide added benefit when it was added to

levetiracetam. There is no evidence at this time to support that Briviact® is safer or more effective than the currently available, more cost effective medications.

**Recommendation:**

- Add Briviact® tablets, oral suspension to non-preferred.
- Move Tegretol® suspension to preferred. Tegretol® tablets remain non-preferred.
    - Clinical criteria
        - Briviact: The patient has been started and stabilized on the requested medication (Note: Samples are not considered adequate justification for stabilization.) OR the diagnosis is adjunctive therapy of partial-onset seizures and the patient has had a documented side effect, allergy, treatment failure/inadequate response or a contraindication to at least TWO preferred anticonvulsants, one of which is levetiracetam.
    - Add Tegretol tabs to Carbatrol criteria.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

**e) Jentadueto® XR (linagliptin & metformin extended- release)**

- Jentadueto® XR is a fixed-dose combination tablet that contains linagliptin (an inhibitor of the dipeptidyl peptidase-4 [DPP-4] enzyme) and metformin (a member of the biguanide class). The tablets consist of an extended-release metformin core tablet that is coated with the immediate-release drug linagliptin. It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate. Jentadueto® XR should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. Furthermore, it has not been studied in patients with a history of pancreatitis; and, it is not known if patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using Jentadueto® XR. There is some evidence that Jentadueto® XR is more effective when compared with each individual ingredient separately. However, there is no evidence at this time to support that Jentadueto® XR is safer or more effective than the other

currently available, more cost effective medications, including the use of each individual ingredient taken together.

**Recommendation:**

- Add Jentadueto® XR to non-preferred with quantity limit 1 tablet/day
  - Clinical criteria:
    - Jentadueto® XR: patient has had an inadequate response with Tradjenta and Metformin XR monotherapy OR patient has been started and stabilized on Tradjenta and Metformin XR combination therapy AND patient is unable to take Tradjenta and Metformin XR as the individual separate agents.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

**f) Nuplazid® (pimavaracetam)**

- Nuplazid® is indicated for treatment of hallucinations and delusions associated with Parkinson's disease psychosis. Pimavanserin, the active ingredient of Nuplazid®, is an atypical antipsychotic. The mechanism of action for its approved indication is not known; however, it is thought to be mediated through a combination of inverse agonist and antagonist activity at serotonin 5-HT2A receptors and to a lesser extent at serotonin 5-HT2C receptors.

**Recommendation:**

- Add Nuplazid® to non-preferred with quantity limits of 2 tablets/day.
- Move Aripiprazole tablets to preferred with quantity limit = 1.5 tabs/day (5mg, 10mg, & 15mg).
- Add Quetiapine ER to non-preferred.
  - Clinical criteria
    - Nuplazid: The diagnosis or indication is the treatment of hallucinations/delusions associated with Parkinson's Disease psychosis.
    - Add Quetiapine ER to the Seroquel XR criteria.
    - Remove the Abilify, aripiprazole clinical criteria.

- Add Abilify to Clozaril, Geodon, Risperdal, and Zyprexa clinical criteria**:** patient has a documented intolerance to the generic equivalent.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

**g) Xiidra® (lifitegrast)**

- Lifitegrast, the active ingredient of Xiidra®, is a lymphocyte function-associated antigen-1 (LFA-1) antagonist. Lifitegrast binds to the integrin LFA-1, a cell surface protein found on leukocytes, and blocks the interaction of LFA-1 with its cognate ligand intercellular adhesion molecule-1 (ICAM-1). ICAM-1 may be overexpressed in corneal and conjunctival tissues in dry eye disease. LFA-1 and ICAM-1 interaction can contribute to the formation of an immunological synapse resulting in T-cell activation and migration to target tissues. The exact mechanism of action in dry eye disease is not known. Xiidra® is indicated for the treatment of signs and symptoms of dry eye disease. There is no evidence at this time to support that Xiidra® is safer or more effective than the currently available, more cost effective medications.

**Recommendation:**

- Add Xiidra® solution to non-preferred with quantity limit 60vials/30 days
- Add Refresh P.M Ointment, Refresh Lacri-lube Ointment and Refresh PLUS Sol to preferred.
- Remove: “And all other generics” from list of preferred agents.
    - Clinical criteria
        - Xiidra**:** The patient has a diagnosis of Dry Eye Disease AND has a documented side effect, allergy or treatment failure to Restasis.
        - Remove Limitations-OTC branded ocular lubricants are not covered (as part of DVHA’s comprehensive OTC policy). There is no PA opportunity for branded OTC ocular lubricants.

*Public Comment:* Awni Swais, Shire: Highlighted the attributes of Xiidra®.

**Board Decision:** The Board unanimously approved the above recommendation.

**h) Xtampza® (oxycodone extended-release)**

- Oxycodone, the active ingredient of Xtampza® ER, is an opioid agonist. It is a full opioid agonist and is relatively selective for the mu receptor, with the principal therapeutic action being analgesia. As with all full opioid agonists, there is no ceiling effect to analgesia for oxycodone. Xtampza® is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Due to the risk of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, Xtampza® ER should be reserved for use in patients for whom alternative treatment options (e.g. non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Xtampza® ER is not indicated as an as-needed (prn) analgesic. Xtampza® ER should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain. Xtampza® ER is to taken twice daily with food. It is recommended to use the lowest effective dose for the shortest duration to meet individual patient treatment goals. The max daily dose is 288mg per day. An enriched-enrollment, randomized-withdrawal, double-blind, placebo-controlled, parallel-group study was performed to assess the safety and efficacy of Xtampza® ER in patients. There is no evidence at this time to support that Xtampza® ER is safer or more effective than the currently available, more cost effective medications or other abuse deterrent formulations.

**Recommendation:**

- Add Xtampza® ER to non-preferred with quantity limit of 60 tablets/strength/30 days.
    - Clinical criteria
        - Oral Non-Preferred (except methadone & tramadol containing products): The patient has had a documented side effect, allergy, or treatment failure to morphine sulfate CR 12hr tablet (generic) AND generic fentanyl patch. (If a product has an AB rated generic, there must have been a trial of the generic) AND if there is a history of substance abuse, the patient must have a documented side effect, allergy, or treatment failure to the

preferred abuse deterrent formulation (Embeda) before OxyContin or Xtampza ER will be approved.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

**i) Probuphine® (buprenorphine)**

- Defer until review of Opiate Dependence Agents Therapeutic Drug Class.

**Recommendation:** Deferred recommendation until therapeutic drug class review.

*Public Comment:* No public comment.

**Board Decision:** Deferred decision until therapeutic drug class review.

**9. Therapeutic Drug Classes – Periodic Review: Jeffery Barkin,MD, Change Healthcare and Laurie Brady, RPh, Change Healthcare**

**a) Androgenic Agents**

- No new drugs
- No significant changes

**Recommendation:**

- Change Natesto clinical criteria to: The patient has had a documented side effect, allergy, or treatment failure to AndroGel® Gel and Androderm.
- Remove the 1% from Androgel Pump- no longer being manufactured.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

**b) Antifungals, Topical**

- No new drugs
- No significant changes

**Recommendation:**

**Antifungals- Topical**

- Move Econazole 1% to non-preferred.
- Move Ciclodan to non-preferred.

- Move Nystatin w/ triamcinolone to non-preferred.
- Remove Pedi Dri® from PDL since it is no longer a rebatable product.
- Remove Lotrisone® lotion since it is no longer available.
    - Clinical criteria
        - Remove Ketoconazole Foam criteria.
        - Remove Limitations comment under criteria.
        - Rename all brands to All Non-Preferred Agents.

**Antifungals- Onychomycosis**

- Add Ciclodan to non-preferred.
    - Clinical criteria
        - Add Ciclodan to the Jublia, Kerydin and Penlac Sol criteria.

*Public Comment:* No public comment

**Board Decision:** The Board unanimously approved the above recommendation.

**c) Anti- parasitics, Topical**

- No new drugs
- No significant changes

**Recommendation:**

- Add Elimite cream to non-preferred.
- Remove the OTC step on Natroba and Sklice.
    - Clinical criteria
        - Remove clinical criteria for Natroba and Sklice.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

**d) Antivirals, Oral**

- Herpes simplex virus type 1 (HSV-1) and herpes simplex virus type 2 (HSV-2) belong to a family of DNA viruses that include other viral types such as cytomegalovirus, Epstein Barr virus, and varicella-zoster virus (VZV). Following primary infection, herpes viral infections remain in a latent state. Reactivation often occurs, thereby resulting in recurrent infections that may or may not be accompanied by symptoms. HSV-1 is commonly contracted during childhood or adolescence, and is often transmitted in oral secretions. HSV-2 is generally transmitted through sexual activity. Genital herpes can result from infection with

either HSV-1 or HSV-2, though HSV-2 has been identified as the main culprit in this country. Varicella-zoster virus (VZV) is a herpes virus that induces a primary infection (varicella, or chickenpox), establishes a latent state, and can reactivate to cause recurrent disease (herpes zoster, or shingles). Antiviral therapy can lessen the severity and duration of pain and promote healing of skin lesions. A 2016 Cochrane Review by Heslop et al[103] included 26 randomized controlled trials to assess for the safety and efficacy of the various treatments for first-episode genital herpes on the duration of symptoms and time to recurrence. Topical acyclovir was not shown to reduce symptoms or reduce the # of days to recurrence. The CDC continues to discourage its use, and oral antivirals remain the recommended first-line treatment.

- For the 2016/17 influenza season, the Advisory Committee on Immunization practices (ACIP) recommends vaccination for everyone > 6 months unless it is contraindicated. The nasal spray vaccine was not recommended this season. Tamiflu/Relenza are recommended by the CDC as early as possible for confirmed cases but should not, however, be used as a substitute for early influenza vaccination on an annual basis. Prophylaxis with amantadine and rimantadine are no longer recommended because of reports of widespread resistance.

**<u>Recommendation</u>:**

Antiviral, Oral

- Add Acylovir suspension to non-preferred. Acyclovir tablets and capsules will remain preferred.
- Add Zovirax suspension (age ≤ 12 yrs) to preferred.
    - Clinical criteria
        - Acyclovir suspension: The patient has a medical necessity for a non-solid oral dosage form AND has a documented intolerance to brand Zovirax suspension.
        - Zovirax suspension (age > 12 yrs): The patient has a medical necessity for a non-solid oral dosage form.

Antiviral, Topical

- Clinical criteria
    - Remove Acyclovir, Zovirax clinical criteria.
    - Update the Denavir, Acyclovir, Xerese, Zovirax clinical criteria to: The patient has a diagnosis of oral herpes simplex infection and a failure of both an oral antiviral and Abreva OTC AND For approval of generic acyclovir ointment, the patient must also have documented intolerance to brand Zovirax.

*Public Comment:* No public comment

**Board Decision:** The Board unanimously approved the above recommendation.

**e) Atopic, Dematitis**

- Atopic dermatitis, or eczema, is a common inflammatory condition of the skin that has a significant impact on quality of life for affected children and adults. It affects approximately 5-20% of children worldwide; the prevalence in the US is approximately 11%. There is no cure for atopic dermatitis; however, the standard treatment approach for atopic dermatitis consists of avoiding exacerbating factors (such as harsh soaps/detergents or heat; treating skin infections; and avoiding stress), restoring the skin barrier function and hydration of skin (using antihistamines to control pruritus, emollients for skin hydration), patient education, pharmacological treatment of skin inflammation, and avoidance/maintenance of super infections. Both pimecrolimus (Elidel®) and tacrolimus (Protopic®) are indicated as *second line* therapy for atopic dermatitis, as short term and non-continuous chronic treatment in non-immunocompromised adults and children 2 years of age or older who have failed to respond adequately to other topical prescription treatments for atopic dermatitis or when these treatments are not advisable. Both treatments currently have an FDA-mandated box warning indicating long-term safety of either calcineurin product has not been established.

**Recommendation:**

- Remove Elidel and Protopic (age <2 yrs) from the PDL.
  - Clinical criteria
    - Criteria for Approval (requests will be approved for up to 1 year): The patient has a diagnosis of atopic dermatitis (eczema). AND The patient has had a documented side effect, allergy, or treatment failure with at least one moderate to high potency topical corticosteroid within the last 6 months. AND The quantity requested does not exceed 30 grams/fill and 90 grams/6 months. AND If the request is for generic tacrolimus ointment, the patient has a documented intolerance to brand Protopic. **Note:** Use in children less than 2 years of age is not indicated. Protopic® ointment 0.1% is not indicated for use in children, only the 0.03% strength.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

**f) H.Pylori**

- No new drugs
- No significant changes

**Recommendation:**

- Remove Helidac from the PDL since it is not longer available.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

**g) Chemical Dependency**

- New drug- Probuphine® subdermal implant
  - Buprenorphine implants (Probuphine®) should be used only in patients who are opioid tolerant. Each dose consists of 4 implants that should be in place for 6 months; after 6 months, the implants should be removed. New implants may be inserted subdermally in an area of the inner side of either upper arm that has not been previously used at the time of removal, if continued treatment is desired. Patients must meet the following criteria for buprenorphine implants (Probuphine®) use: achieved and sustained prolonged clinical stability on transmucosal buprenorphine; are currently on a maintenance dose of ≤8mg per day of Subutex® or Suboxone® SL or its transmucosal buprenorphine product equivalent; and stable transmucosal buprenorphine dose for 3 months or longer without any need for supplemental dosing or adjustments.
- No other significant changes

**Recommendation:**

**Alcohol Dependency**

- Remove Campral and Revia from the PDL.
- Move Vivitrol®(naltrexone for extended-release injectable suspension) (QL = 1 injection (380 mg) per 30 days) to Preferred Agent after Clinical Criteria are Met (QL = 1 injection (380 mg) per 30 days).

**Opiate Dependency**

- Move -Vivitrol® (naltrexone for extended-release injectable suspension) (QL = 1 injection (380 mg) per 30 days) to preferred agent after Clinical Criteria are Met.
- Add Probuphine® (buprenorphine) subdermal implant (QL=4 implants per 6 months, Maximum length of therapy = 1 year) to non-preferred.
    - Clinical criteria
        - Add **Probuphine:** Patient must have achieved and sustained prolonged clinical stability on transmucosal buprenorphine AND is currently on a maintenance dose of ≤ 8mg per day of Suboxone® or its transmucosal buprenorphine product equivalent (defined as stable on a transmucosal buprenorphine dose of ≤ 8mg for 3 months or longer without any need for supplemental dosing or adjustments) AND the provider and patient are both enrolled in the Probuphine® REMS program AND clinical justification must be provided detailing why the member cannot use a more cost effective buprenorphine formulation. **Note:** Probuphine® will be approved as a medical benefit ONLY and will NOT be approved if billed through pharmacy point of sale. Probuphine® will not be approved for new entrants to treatment. Initial approval will be granted for 6 months with extension considered for an additional 6 months (There is no clinical experience with insertion of Probuphine® beyond a single insertion in each arm).
        - Updated Vivitrol: There must be a documented trial of oral naltrexone AND Patient should be opiate free for > 7 -10 days prior to initiation of Vivitrol. If the diagnosis is alcohol dependence, the patient should not be actively drinking at the time of initial Vivitrol administration.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

## 10. New Managed Therapeutic Drug Classes

- None at this time

## 11. General Announcements:

Selected FDA Safety Alerts

- **Products Containing Belladonna Extract by Raritan Pharmaceuticals: Recall - Possible Belladonna Alkaloids**

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm530642.htm

- **General Anesthetic and Sedation Drugs: Drug Safety Communication - New Warnings for Young Children and Pregnant Women**
  http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm533195.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
- **FDA approves Jardiance to reduce cardiovascular death in adults with type 2 diabetes**
  http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm531517.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

**12. Adjourn:** Meeting adjourned at 8:32p.m.